(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 768 043 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
19.11.2003 Bulletin 2003/47

(51) Int Cl.7: **A61K 31/70**, A61K 31/715, A23L 1/307, A23L 1/09, A61K 31/045, A23L 1/29

(21) Application number: **96202877.5**

(22) Date of filing: **15.10.1996**

(54) **Diabetic nutritional product having controlled absorption of carbohydrate**

Nährmittel für Diabetiker mit gesteuerter Absorption der Kohlenhydrate

Produit de nutrition pour les diabétiques avec contrôle d'absorption de glucides

(84) Designated Contracting States:
AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE

(30) Priority: **16.10.1995 US 5468**

(43) Date of publication of application:
16.04.1997 Bulletin 1997/16

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WO-A-96/31129
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EP 0 768 043 B1

Printed by Jouve, 75001 PARIS (FR)

Description

[0001] The present invention concerns a nutritional composition for use by diabetics which results in a controlled or sustained absorption of carbohydrate during digestion.

[0002] Current diet recommendations for people with diabetes are 30% or less energy intake from total fat and 10 - 20% from protein American Diabetes Association ,1994; "Nutritional recommendation and principles for people with diabetes mellitus". Diabetes Care 17:519-522). A key goal of these recommendations is maintenance of "near-normal blood glucose." It has been shown that refined foods result in more rapid starch digestion and concomitantly a higher blood glucose elevation than conventionally cooked foods (Brand et al., Diabetes Care 14:95-101, 1991).

[0003] In general, factory processed (refined) foods produce a higher glycemic index than do unprocessed cooked foods. Many refined liquid foods are high in fat (i.e.,40% or greater of total calories as fat) to attenuate their glycemic index. Thus, achieving the American Diabetic Association recommendations of a moderate to low fat diet using refined food products is dificult without substantially increasing blood glucose peaks. Refined diabetic product examples include:

Glucerna®, marketed by Ross Laboratories, contains 50% of calories from fat, 17% from protein, and 33% from carbohydrate.
Glytrol®, marketed by Clintec, contains 42% of calories from fat, 18% from protein, and 40% from carbohydrate.
Resource®, marketed by Sandoz, contains 40% of calories from fat, 24% from protein, and 36% from carbohydrate.

[0004] Thus, in the prior art, refined products have minimized elevations in postprandial blood glucose primarily with low carbohydrate levels and high fat levels. The above products have avoided sucrose to minimize negative effects for diabetics (see also U.S. patent nos. 5,292,723 and 4,921,877).

[0005] WO 96/31129 describes a therapeutic food composition for the treatment of diabetes, containing complex carbohydrate, protein and fat. It forms part of the state of the art only under Article 54(3) EPC.

[0006] Heretofore, a refined diabetic product with 0 to 45% fat and a carbohydrate component with sucrose having controlled or sustained absorption has been unknown.

[0007] The present invention is directed to a nutritional composition containing moderate to low fat and a carbohydrate component containing a combination of ingredients that provide a fast, moderate, and slow absorption of carbohydrate upon consumption which results in a sustained release of carbohydrate without excessive blood glucose peaks. Accordingly, the present invention is directed to a nutritional composition for the dietary management of diabetics comprising

(a) a protein component comprising 1 to 50 % of total caloric value;
(b) a fat component comprising 0 to 45% of total caloric value;
(c) a carbohydrate component comprising 1 to 90% of total caloric value wherein said carbohydrate component comprises

(i) a rapidly absorbed fraction comprising glucose, one or more rapidly absorbed disaccharides containing a glucose unit, or a mixture thereof, wherein said fraction includes sucrose;
(ii) a moderately absorbed fraction comprising one or more moderately absorbed non-glucose monosaccharides, non-glucose-containing disaccharides, glucose-containing polysaccharides, or mixture thereof;
(iii) a slowly absorbed fraction comprising one or more slowly absorbed glucose-containing polysaccharides,; and

(d) fiber.

[0008] As used herein, the term "rapidly absorbed" means glucose and disaccharides which contribute directly to elevation in blood glucose ,e.g., maltose, and sucrose; the term "moderately absorbed" means mono- and disaccharides, e.g., fructose and mannose, that do not contribute directly to elevation of blood glucose and those polysaccharides, both soluble and insoluble (e.g., starches), containing at least 30 molar % glucose units that release a majority of their glucose upon incubation in pancreatic amylase and amyloglucosidase at 37°C in 20 minutes or less as described by Cummings and Englyst AJCN 61(Suppl):938S-945S; the term "slowly absorbed" means those polysaccharides containing at least 30 molar % glucose units, having a glycemic index greater than 2, and that release a majority of their glucose in greater than 20 minutes upon incubation in pancreatic amylase and amyloglucosidase at 37°C as described above; and the term "polysaccharide" means a carbohydrate having three or more monomers.

[0009] The nutritional composition of the invention utilizes a carbohydrate component the results in a controlled or sustained absorption of carbohydrate upon consumption such that excessive blood glucose peaks are avoided. The

combination of carbohydrate fractions disclosed herein provides a balanced mix so that the digestive tract absorbs a substantially constant amount of carbohydrate over time.

[0010] The carbohydrate component comprises 1 to 90% of total calories, preferably 20 to 80% of total calories, and more preferably 30 to 80% of total calories.

[0011] The rapidly absorbed fraction of the carbohydrate component typically comprises 1 to 95 weight (wt) % of total carbohydrate component, preferably 5 to 85 wt.%, and more preferably 20 to 75 wt %. When referring herein to the composition of the carbohydrate component, all weight percentages are on a dry weight basis. It is an advantage of the present invention that the rapidly absorbed fraction contains sucrose. Sucrose has been specifically avoided in prior art compositions such as described in U.S. patent no. 5,292,723. Sucrose, in addition to being rapidly absorbed, imparts a sweet taste to the composition thereby increasing palatability. Other disaccharides that may be used as part of the rapidly absorbed fraction are those that contain glucose and thus release glucose upon cleavage of the bond connecting the two monomeric crabohydrate moieties making up the disaccharide. Examples of such disaccharides include, lactose, maltose, galactose.

[0012] The moderately absorbed fraction of the carbohydrate component typically comprises about 1 to 95 weight (wt) % of total carbohydrate component, preferably 5 to 85 wt %, and more preferably 20 to 75 wt %. The monosaccharides and disaccharides that are considered moderately absorbed are non-glucose monosaccharides and non-glucose-containing disaccharides that contribute to blood glucose levels indirectly, i.e., after a metabolic event occurs, e.g., conversion into glucose by the liver. Examples of such moderately absorbed carbohydrates include mannose, fructose, and the like. The moderately absorbed carbohydrate may also be certain polysaccharides that contain glucose units (monomers). Examples of such moderately absorbed carbohydrates include maltodextrins that have a dextrose equivalent of 15 or lower, white flour, wheat flour, certain starches.

[0013] The slowly absorbed fraction of the carbohydrate component typically comprises 1 to 95 weight (wt) % of total carbohydrate component, preferably 5 to 85 wt %, and more preferably 20 to 75 wt %. At least one of the slowly absorbed polysaccharides in liquid products is raw (uncooked or native) corn starch. For twenty years, raw cornstarch has been used to help patients with glycogen storage disease to prevent hypoglycemia (see, for example, P.A. Crapo, et al. (1976). Diabetes 25:741-747; J.I. Wolfsdorf et al., (1990). AJCN 52:1043-1050; D.J.A. Jenjins et al., (1984). Lancet 2:388-391; Y-T Chen et al., (1984). N> Engl. J. Med. 31:171-175; and G.P.A. Smit et al., (1984). Pediatr. Res. 18:879-881). Typical quantities of raw cornstarch fed for glycogen storage disease are 1.75-2.5 grams (g) cornstarch per kilogram (kg) of body weight (wt) every four hours (see, P.H. Parker et al. (1993). Ann. Rev. Nutr. 13:83-109). In the present invention raw cornstarch is used for the purpose of minimizing blood glucose response instead of the prior art use of preventing hypoglycemia for glycogen storage disease. Other slowly absorbed polysaccharides within the scope of the invention include high amylose corn starch (i.e., an amylose content of greater than 40% by weight), a modified starch which gives a glycemic index less than 80 (preferably less than 60), most raw cereals, some pastas. For solid or semi-solid products within the scope of the invention, the slowly absorbed polysaccharide can be any of the aforementioned polysaccharides or mixtures thereof, although the presence of raw corn starch is optional. For such solid or semi-solid products the slowly absorbed polysaccharide preferably comprises high amylose corn starch, modified starch (as described above), or a mixture thereof. A preferred slowly absorbed carbohydrate is Novelose resistant starch which is a high amylose corn starch available from National Starch.

[0014] The term "fiber" refers to fibers and non-absorbant carbohydrates that have a glycemic index less than 2. The fiber comprises 1 to 95 weight (wt) % of total carbohydrate, preferably 5 to 85 wt %, and more preferably 10 to 50 wt %. The fiber can be soluble, insoluble, fermentable, non-fermentable, or any combination thereof. The fiber can be, for example, soy fiber, pectin, certain resistant starches, oligofructose, inulins, oat fiber, pea fiber, guar gum, gum acacia, modified cellulose.

[0015] The fat component is present in a low to moderate amount, for example 0 to 45% of total calories, preferably 10 to 40% of total calories, and more preferably 15 to 35% of total calories. The fat component can be any lipid or fat known in the art to be suitable for use in nutritional compositions. Typical fats include milk fat, safflower oil, canola oil, egg yolk lipid, olive oil, cotton seed oil, coconut oil, palm oil, palm kernel oil, soybean oil, sunflower oil, fish oil and fractions of all above oils derived thereof such as palm olein, medium chain triglycerides (MCT), and esters of fatty acids wherein the fatty acids are, for example, arachidonic acid, linoleic acid, palmitic acid, stearic acid, docosahexaenoic acid, eicosapentaenoic acid, linolenic acid, oleic acid, lauric acid, capric acid, caprylic acid, caproic acid. High oleic forms of various oils are also contemplated to be useful herein such as high oleic sunflower oil and high oleic safflower oil.

[0016] The protein component is present in an amount, for example, of 1 to 50% of total calories, preferably 10 to 40% of total calories, and more preferably 15 to 30% of total calories. The protein can be any protein and/or amino acid mixture known in the art to be suitable for use in nutritional compositions. Typical proteins are animal protein, vegetable protein such as soy protein, milk protein such as skim milk protein, whey protein and casein, and amino acids (or salts thereof) such as isoleucine; phenylalanine, leucine, lysine, methionine, threonine, tryptophan, arginine, glutamine, taurine, valine. Preferred protein sources are whey protein, sodium caseinate or calcium caseinate optionally

supplemented with amino acids. For some applications a preferred protein source is hydrolyzed protein (protein hydrolysate) optionally supplemented with amino acids.

[0017] The protein hydrolysate useful in the invention may be any suitable protein hydrolysate utilized in a nutritional formula such as soy protein hydrolysate, casein hydrolysate, whey protein hydrolysate, other animal and vegetable protein hydrolysates, and mixtures thereof. The protein hydrolysate of the composition of the invention is preferably a soy protein, whey protein, or a casein protein hydrolysate comprising short peptides and amino acids, optionally supplemented with additional amino acids. In a preferred embodiment, the protein hydrolysate useful in the invention contains a high percentage of free amino acids (e.g. greater than 40%) and low molecular weight peptide fragments.

[0018] The hydrolyzed protein of the composition of the invention is also preferably supplemented with various free amino acids to provide a nutritionally balanced amino content. Examples of such free amino acids include L-tryptophan, L-methionine, L-cystine, L-tyrosine, and L-arginine.

[0019] The nutritional compositions of the invention preferably contains vitamins and minerals. Vitamins and minerals are understood to be essential in the daily diet and these should be present in. Those skilled in the art appreciate that minimum requirements have been established for certain vitamins and minerals that are known to be necessary for normal physiological function. Practitioners also understand that appropriate additional amounts (overages) of vitamin and mineral ingredients need to be provided to nutritional compositions to compensate for some loss during processing and storage of such compositions. The composition of the invention preferably contains nutritionally significant amounts of vitamins and minerals. It is preferred that the composition contain at least 100% of the U.S. Recommended Daily Allowance (RDA) in 500 to 4000 cal of composition, preferably to 600 to 3000 cal of composition.

[0020] To select a specific vitamin or mineral compound to be used in the composition requires consideration of that compound's chemical nature regarding compatibility with the processing and shelf storage.

[0021] Examples of minerals, vitamins and other nutrients optionally present in the composition of the invention include vitamin A, vitamin B_6, vitamin B_{12}, vitamin E, vitamin K, vitamin C, vitamin D, inositol, taurine, folic acid, thiamine, riboflavin, niacin, biotin, pantothenic acid, choline, calcium, phosphorous, iodine, iron, magnesium, copper, zinc, manganese, chloride, potassium, sodium, beta-carotene, nucleotides, selenium, chromium, molybdenum, and L-carnitine. Minerals are usually added in salt form. In addition to compatibility and stability considerations, the presence and amounts of specific minerals and other vitamins will vary somewhat depending on the intended consumer population.

[0022] The composition of the invention also typically contains emulsifiers and/or stabilizers such as lecithin (e.g., egg or soy), modified lecithin (e.g., enzyme or acetylated), carrageenan, xanthan gum, mono- and diglycerides, guar gum, carboxymethyl cellulose, stearoyl lactylates, succinylated monoglycerides, sucrose esters of fatty acids, diacetyl tartaric acid esters of monoglycerides, polyglycerol esters of fatty acids, or any mixture thereof.

[0023] The composition of the invention optionally contains one or more natural or artificial flavorants to enhance palatability. Any flavorant used in the art can be included such as strawberry; cherry; chocolate; orange; coconut; vanilla; spices such as nutmeg, cinnamon; citric acid; in some instances when natural flavorants are used, such as coconut pieces, the ingredient will contribute to the overall nutritional profile of the composition, i.e., contribute to the quality and quantity of the fat, protein and/or carbohydrate components.

[0024] The composition of the invention also optionally contains other miscellaneous ingredients that may contribute to the nutritional profile of the composition and/or impart desirable palatability characteristics such as enhanced flavor or mouth feel. Such ingredients include peanuts, raisins, cheese powder, vinegar, salt, sodium bicarbonate. For bars, the composition is typically enrobed with chocolate or a flavored (e.g. chocolate, vanilla, strawberry, etc.) coating.

[0025] The composition of the invention also optionally contains natural or artificial colors to enhance aesthetic appeal.

[0026] The compositions of the invention can be in several physical forms such as liquid enteral nutritional formulas or drinks for adults or children, a semi-solid form such as a pudding or a solid form such as a nutritional bar or cookie.

[0027] The composition of the invention also contains water; however, the amount of water can vary substantially depending upon the desired physical form. For example the water content can vary from 2 to 92 wt % of total composition.

[0028] The composition of the invention can be prepared by use of standard techniques known in the nutritional art, for example by techniques analogous to those disclosed in U.S. Patents 4,670,268; 4,497,800; 4,900,566; 5,104,677; 5,389,395; and 5,223,285; And Chocolate, Cocoa and Confectionery: Science and Technology, 3rd Edition, Bernard W. Minifie, Van Nostrand Reihhold, New York, 1989, pp 502-506; the disclosures of which are incorporated herein by reference. For nutritional bars and cookies it is typically desired to bake the composition after physical forming.

[0029] The composition of the invention can be sterilized, if desired, by techniques known in the art, for example, heat treatment such as autoclaving or retorting, or irradiation, or processed and packaged by aseptic technology.

[0030] The composition of the invention can be packaged in any type of container or package known in the art to be useful for storing nutritional products such as paper, glass, lined paperboard, plastic, or coated metal cans.

[0031] The composition of the invention can be nutritionally complete. By the term "nutritionally complete" is meant that the composition contains adequate nutrients to sustain healthy human life for extended periods.

[0032] The present invention is also directed to a method for controlling blood glucose levels in a subject comprising administering the nutritional composition of the invention to said subject The subjects are most preferably humans; however, other mammals, especially primates, are also contemplated. The administration is enteral, i.e., oral or tube feeding. The subjects are those in need of treatment, such as diabetics or those susceptable to diabetes. Upon contact with the digestive system, the composition of the invention provides a sustained absorption of carbonydrate over time such that the blood glucose levels remain relatively constant (e.g., does not vary by more than 75%) during the period of time that the composition is being digested. Thus, the composition of the invention can be said to provide a steady, time-release source of glucose.

[0033] In the process of manufacturing a confectionery or nutritional bar, use is made of cold forming or extrusion. Other types of extrusion processes are used in the food industry, and is necessary to clearly demarcate the differences between the cold forming or extrusion used in the manufacture of confectionery type bars, and the process of cooking extrusion used in the manufacture of other types of shaped or formed food objects, since both are often referred to as "extrusion."

[0034] In the process of cold forming/extrusion, the mix required consists of a blend of powders, some or all of which are capable of absorbing water (moisture) or otherwise hydrating, and concentrated solutions of various other ingredients, such as the carbohydrate. The powders absorb water from the concentrated solutions and the individual ingredients in the powder part of the mixture then hydrate. The hydrated molecules (which are generally proteins or complex carbohydrates such as starches) then exhibit affinity through the formation of weak intermolecular forces which can be electrostatic in nature, and can include bonds such as hydrogen bonds as well as van der Waals forces. The carbohydrate (or other) constituent of the original liquid remains entrained in the complex of hydrated molecules, as may other materials (such as fats) that are added to the mixture. A measure of the emulsifying power of the hydrated molecules is indeed to see how much fat or oil can be thus entrained or coated with protein, since the hydrophobic nature of fat or oil makes greater demands on the strength of interaction between the hydrated molecules.

[0035] It is equally possible, though less desirable, to mix the hydrateable materials and the carbohydrate (or other) constituents and then add water. The quality and integrity of product thus produced may be inferior due to poor dispersion.

[0036] Addition of water alone to hydrateable protein gives a mass that lacks adequate integrity and cohesion and is not suitable for cold forming; this limitation is not necessarily present for hydrateable carbohydrates.

[0037] The process above is intended to give a plastic mass which can then be shaped, without further physical or chemical changes occurring, by the procedure known as cold forming or extrusion. In this process, the plastic mass is forced at relatively low pressure through a die which confers the desired shape and the resultant extrudate is then cut off at an appropriate position to give products of the desired weight.

[0038] The mass may, for example, be forced through a die of small cross-section to form a ribbon, which is carried on a belt moving at a predetermined speed under a guillotine type cutter which operates at regular intervals. The cutter, in this case, generally consists of a sharpened blade so adjusted that it cuts through the ribbon but not the underlying belt, but may also consist of a wire. In both cases, the principle is the same; the cutting process occurs at intervals that permit the moving ribbon to be cut into pieces of equivalent weight and dimensions. Generally, this is achieved by timing the cutting strokes and maintaining belt speed at an appropriate level, but there also exist computer controlled versions of this mechanism which offer greater versatility. Alternatively, the mass may be forced through a die of large cross-section and the cut at die level into slices by an oscillating knife or wire, which drop onto a moving belt and are thus transported away. The mass may also be extruded as a sheet, which is then cut with a stamp type cutter into shapes that are appropriate, such as a cookie type cutter. Finally, the mass may also be forced into chambers on a rotary die equipped with an eccentric cam that forces the thus-formed material out of the chamber at a certain point in the rotation of the cylindrical die.

[0039] After shaping, the formed product is moved by a transfer belt or other type of material conveyor to an area where it may be further processed or simply packaged. In general, a nutritional bar of the type described would be enrobed (coated) in a material that may be chocolate, a compound chocolate coating, or some other type of coating material. In all such cases, the coating material consists of a fat that is solid at room temperature, but that is liquid at temperatures in excess of, e.g., 31.1°C (88°F), together with other materials that confer the organoleptic attributes. The coating is thus applied to the bar while molten, by permitting the bar to pass through a falling curtain of liquid coating, at the same time passing over a plate or rollers which permit coating to be applied to the under surface of the bar, and excess coating is blown off by means of air jets, Finally, the enrobed bar passes through a cooling tunnel where refrigerated air currents remove heat and cause the coating to solidify.

[0040] In all these variations, the requirement is that the plastic mass be relatively soft, possessed of sufficient integrity to maintain its form after shaping.

[0041] The process of cold forming, often ambiguously referred to as "extrusion", is thus a distinct process, with the characteristics described below:

1) Low temperature. Generally the process occurs at ambient temperature of 15,6°C to 29,4°C (60°F to 85°F), though in some cases it is desirable to cool the extrusion equipment down to lower temperatures, and occasionally, when manufacturing products based on sucrose, or nutritional products of similar physical characteristics, the extruder may be heated to temperatures in excess of 37,8°C (100°F). However, for the manufacture of nutritional products, temperatures are usually kept at ambient or occasionally slightly lower.

2) Low pressure. The pressure is required only to force the mass through the die, and pressure in the die will generally remain below 4,1 bar (60 lbs./sq. inch).

3) Reliance on the physical properties of the mass fed to the extruder to give the final form to the product.

4) Absence of heat- or pressure-mediated chemical or physical reactions or changes; the only changes occurring in the product are those caused by hydration during the initial mixing procedure.

[0042] Cooking extrusion is a technology that is entirely distinct from confectionery type extrusion; the only relationship between these two technologies, which have diametrically opposed aims in terms of food manufacture, is the word "extrusion", which is a word that is commonly used in the plastics and aluminum industries, in both of which extrusion processes are used to impart form to materials. The characteristics of cooking extrusion are:

1) High temperature. The product must exit the extruder at temperatures in excess of 100°C (212°F) since the water present must flash off as vapor. The high temperature is achieved in a long barrel, into which product is positively fed from a hopper or conditioning cylinder. In the barrel, material can be heated by injection of high pressure steam, as well as by heating of the barrel itself. In addition, the screw auger in the barrel, and the configuration of the barrel itself, are designed to create high pressures which also have a heating effect. Temperatures within the barrel may be as high as 288°C (550°F).

2) High pressure. The equipment is designed to reach pressures of 138 - 207 bar (2000 - 3000lbs./sq. inch) newer cooking extruders may go up to 689,5 bar (10,000 lbs./sq. inch), at which pressure (and resultant temperatures), substances such as lignin can be broken down into edible nutrients.

3) Reliance on the violent depressurization when the product leaves the barrel (through an appropriate die) to give the product a desired physical form, such as expanded, foamy and aerated for snack products, fiber-like for texturized vegetable proteins, and more expanded for other product forms.

4) Dependence on pressure and heat-mediated physical and chemical reactions to impart desired characteristics to the product.

[0043] The following examples are to illustrate the invention but should not be interpreted as a limitation thereon.

Example 1

[0044]

Granola bar	
Formulation (per 100 g)	
Rolled Oats	40g
Raisins	15g
Novelose starch, National Starch	10.6g
Nonfat Dry Milk	7g
Sucrose and, optionally, High Fructose Corn Syrup	7g
Coconut	6g
Water	5.6g
Peanuts	5g
Vegetable Oil	2g
Vinegar	0.9g

(continued)

Granola bar	
Formulation (per 100 g)	
Vitamin Premix	0.5g
Salt	02g
Cinnamon	0.2g
Total Calories:	379
Protein:	11% Calories
Fat:	27% Calories
Carbohydrates:	62% Calories
Total Fiber:	4.1g
Vitamin E: 30 mg	
Vitamin C: 20 mg	
Beta Carotene:	1mg

Processing Procedures

[0045] Cut raisins and peanuts into small pieces; mix with oats, raisins, peanuts and coconut. Heat water to 43.3°C (110°F) and dissolve corn syrup, starch, skim milk powder, salt, vitamin premix, and vinegar. Blend all ingredients together slowly; mix well. Roll out to approximately 1.5cm thick. Bake at 196°C (385°F) for nine minutes. Cool and cut to appropriate size.

Example 2

[0046]

Oatmeal Raisin Cookies	
Formulation (per 100 g)	
Rolled Oats	20.5g
Water	15g
Nonfat Dry Milk	12g
Raisins	12g
Sucrose	7.1g
Novelose starch, National Starch	7g
Wheat Flour	6.8g
High Fructose Corn Syrup	6g
Vegetable Oil	5g
Brown Sugar	4.7g
Maltodextrin	1.5g
Mono and diglycerides	0.8g
Vitamin Premix	0.5g
Sodium Bicarbonate	0.3g
Salt	0.3g
Vanilla flavor	0.2g
Cinnamon	0.2g
Citric acid	0.07g
Nutmeg	0.03g
Total Calories:	379
Protein:	11 % Calories
Fat:	27% Calories
Carbohydrates:	62% Calories

(continued)

Oatmeal Raisin Cookies	
Formulation (per 100 g)	
Total Fiber:	4.1g
Vitamin E: 30 mg	
Vitamin C: 20 mg	
Beta Carotene :	1mg

Processing Procedures

[0047] Mix all dry ingredients together except raisins. Slowly add water and oil, mix well. Add raisins and mix well. Drop portions onto cooking surface. Bake at 177°C (350°F) for 15 minutes.

Example 3

[0048]

Nutritional Snack Bar	
Formulation (per 100g)	
Soy Isolate	40g
Wheat Flour	20g
Novelose Starch, National Starch	11g
Fiber Source	10g
Vegetable Oil	7g
Cheese Powder	6g
Maltodextrin	4g
Vitamin Premix	2g
Total Calories:	376
Protein :	18% Calories
Fat:	33% Calories
Carbohydrates:	49% Calories
Total Fiber:	12.6 g
Vitamin E: 30 mg	
Vitamin C: 20 mg	
Beta Carotene:	1 mg

Processing Procedures

[0049] Blend all ingredients and mix well. Cook and form the product with an extruder. Extruder conditions vary with different equipment.

Example 4

[0050]

Nutritionally Complete Drink	
Formulation	
Milk Protein Concentrate	8.6 g
Vegetable Oil Blend 3.3 g	
Maltodextrin	1.5 g
Novelose Starch, National Starch	6.667 g

(continued)

Nutritionally Complete Drink	
Formulation	
Sucrose	1.8 g
Vanilla Flavor	0.5 g
Lecithin	0.095 g
Mono- and Diglycerides	0.095 g
Choline Chloride	0.074 g
Inositol	0.028 g
Carnitine	0.018 g
Taurine	0.018 g
Potassium Citrate	0.437 g
Magnesium Phosphate	0.173 g
Sodium Chloride	0.08 g
Magnesium Chloride	0.25 g
Sodium Citrate	0.15 g
Ferrous Sulfate	0.01 g
Vitamin Premix	1.844 g
Trace Mineral Premix	0.012 g
Water	84.63 g
Total Calories:	94
Protein:	30% Calories
Fat:	34% Calories
Carbohydrates:	36% Calories
Total Fiber:	2 g
Vitamin E: 30 mg	
Vitamin C: 20 mg	
Beta Carotene:	1 mg

Processing Procedures

[0051] Heat one third water to 43,3°C (110°F), dissolve milk protein completely. Dissolve minerals in one fourth the water at 60°C (140°F) and mix into th eprotein solution. Heat oil to 48,9°C (120°F) mix emulsifiers in the oil and add to the product mixture. Add the rest of the ingredients into the mixture. Heat the product at 118°C (245°F) for 45 seconds. Standardize the product, homogenize, fill a can and retort.

Example 5

[0052]

Nutritionally Complete Pudding	
Formulation I (per 100 ml)	
Nonfat Dry Milk	7.5 g
Vegetable Oil Blend	12 g
Modified Corn Starch	5 g
Sucrose	5 g
Carrageenan	0.016 g
Vanilla Flavor	0.5 g
Sodium Stearoyl-2-lactylate	0.095 g
Yellow Color	0.189 g
Maltodextrin	6 g

(continued)

Nutritionally Complete Pudding	
Formulation I (per 100 ml)	
Cellulose	2.1 g
Magnesium Phosphate	0.165 g
Vitamin Premix	1.84 g
Trace Mineral Premix	0.015 g
Water	80.56 g
Total Calories:	101
Protein:	27% Calories
Fat:	11% Calories
Carbohydrates:	62% Calories
Fiber:	2 g
Vitamin E: 30 mg	
Vitamin C: 20 mg	
Beta Carotene :	1 mg

Processing Procedures

[0053] Heat nine tenths of water to 43,3°C (110°F). Dissolve skim milk powder in water. Heat oil to 60°C (140°F), and add carrageenan and oil soluble vitamins to the oil. Mix oil into the product. Add the remaining ingredients except modified starch, vanilla flavor and vitamin premix. Homogenize the mixture. Add starch slowly. Add vitamin and flavor. Standardize the solids content. Heat in the aseptic units and package in cans.

Formulation II (per 100 ml)	
Nonfat Dry Milk	10.715 g
Vegetable Oil Blend	2.2 g
Novelose starch, National Starch	7.5 g
Sucrose	5 g
Carrageenan	0.016 g
Vanilla Flavor	0.5 g
Sodium Stearoyl-2-lactylate	0.095 g
Yellow Color	0.189 g
Magnesium Phosphate	0.165 g
Vitamin Premix	1.84 g
Trace Mineral Premix	0.015 g
Water	81.94 g
Total Calories:	100
Protein:	15% Calories
Fat:	20% Calories
Carbohydrate:	65% Calories
Total Fiber:	2.3 g
Vitamin E: 30 mg	
Vitamin C: 20 mg	
Beta Carotene:	1 mg

Processing Procedures

[0054] See previous example.

Example 6

[0055]

Peanut Bar	
Formulation (per bar)	
Rice syrup	4.9g (solids)
High amylose native starch (Novelose, National Starch)	5g
Toasted soya beans	
Soy protein isolate	
Sorbitol syrup 2.5g (solids)	
Sucrose	4.4g
Whey protein concentrate	
Modified palm/palm kernal oil	
Gum arabic	2.5g
Corn syrup/fructose syrup	2.02g(solids)
Chicory oligofructose	1.5g
Peanut butter	
Microcrystalline cellulose	1g
Milk minerals	
Water	
Calcium caseinate	
Lecithin	
Cocoa powder	
Lactose	
Canola oil	
Soy Cotyledon fiber 0.5g	
Minerals	
Sunflower seed oil	
Dextrose (glucose)	
Vitamins	
N&A flavors	
Hydrogenated soya bean oil	
Whey powder	
Natural color	
Total calories:	173
Protein:	9g
Fat:	6.2g
Carbohydrate:	26.3g
Total fiber:	4.7g
Vitamin A 1098 IU	
beta-carotene	
Vitamin D 91 IU	
Vitamin E 65 IU	
Vitamin C 65mg	
Folic acid 103mcg	
Thiamine 0.51mg	
Riboflavin 0.6mg	
Niacin	4.2mg
Vitamin B_6	0.64mg
Vitamin B_{12}	1.9mcg

(continued)

Peanut Bar	
Formulation (per bar)	
Biotin	75mcg
Pantothenic acid	2.1mg
Calcium	215mg
Phosphorous	271mg
Iodine	31 mcg
Iron	3.3mg
Magnesium 67mg	
Zinc	5.1mg
Copper	0.5mg
Manganese	0.76mg
Sodium	182mg
Potassium 434mg	

Processing Procedures

[0056] All dry ingredients are weighed and mixed together in a mixer. All liquid ingredients, i.e., carbohydrate syurps and oils, are slowly added to the preblended dry ingredients. Te powder ingredients begin to absorb water or hydrate. The resultant mixture can be described as a homogenous, sticky or plastic mass which can be shaped without further physical or chemical changes. A bar form is obtained by the cold forming or extrusion process at ambient temperatures, whereby the mixture is forced at low pressures < 4,1 bar (< 60 lbs./sq. inch) through a die and the extrudate is cut off to achieve a specific shape and desired weight. The formed product is transported by a conveyor belt through the enrober to chocolate coat the bar, blower to blow off excess coating, cooling tunnel to solidify coating, then packaged.

Example 7

[0057]

Chocolate Bar	
Formulation (per Bar)	
Rice syrup	7g (solids)
High amylose native 5g starch (Novelose, National Starch)	
Sorbitol syrup	2.5g (solids)
Sucrose	4.4g
Soy protein isolate	
Whey protein concentrate	
Toasted soya beans	
Modified palm/palm kernal oil	
Calcium caseinate	
Gum arabic 2.5g	
Corn syrup/fructose syrup	2.02g(solids)
Chicory oligofructose	1.5g
Peanut butter	
Microcrystalline cellulose	1g
Milk minerals	
Water	
Lecithin	
Cocoa powder	

(continued)

Chocolate Bar	
Formulation (per Bar)	
Lactose	
Canola oil	
Soy Cotyledon fiber 0.5g	
Minerals	
Sunflower seed oil	
Dextrose (glucose)	
Vitamins	
N&A flavors	
Hydrogenated soya bean oil	
Whey powder	
Natural color	
Total calories:	177
Protein:	9.1g
Fat:	5.5g
Carbohydrate:	29.4g
Total fiber:	4.9g
Vitamin A 943 IU	
beta-carotene	
Vitamin D 78 IU	
Vitamin E 67 IU	
Vitamin C 53mg	
Folic acid 86mcg	
Thiamine 0.43mg	
Riboflavin 0.53mg	
Niacin	3.6mg
Vitamin B_6	0.54mg
Vitamin B_{12}	1.6mcg
Biotin	64mcg
Pantothenic acid	1.86mg
Calcium	206mg
Phosphorous	258mg
Iodine	27mcg
Iron	3.6mg
Magnesium 77mg	
Zinc	4.5mg
Copper	0.52mg
Manganese	0.6mg
Sodium	167mg
Potassium 386mg	

Processing Procedures

[0058] Same as previous example.

Example 8

[0059]

Diabetic Bar	
Total calories:	180
Protein:	9g
Fat:	6-7g
Carbohydrate:	22.5g
Total fiber:	5g
Vitamin A 667 IU	
beta-carotene	333 IU
Vitamin D 80 IU	
Vitamin E 60 IU	
Vitamin C 60mg	
Folic acid 80mcg	
Thiamine 0.3mg	
Riboflavin 0.34mg	
Niacin	4mg
Vitamin B_6	0.4mg
Vitamin B_{12}	1.2mcg
Biotin	60mcg
Vitamin K 24mcg	
Pantothenic acid	2mg
Choline	125mg
Inositol	60mg
Calcium	200mg
Phosphorous	200mg
Iodine	30mcg
Iron	3.6mg
Magnesium	80mg
Zinc	3mg
Copper	0.4mg
Manganese	0.75mg
Sodium	200mg
Potassium 430mg	
Chloride 300mg	
Chromium 50mcg	
Molybdenum	25mcg
Selenium 17mcg	
Taurine	38mg
L-carnitine 38mg	

Processing Procedures

[0060] Same as previous example.

Claims

1. A nutritional composition for the dietary management of diabetes comprising

(a) a protein component comprising 1 to 50 % of total caloric value;

(b) a fat component comprising 0 to 45% of total caloric value;
(c) a carbohydrate component comprising 1 to 90% of total caloric value wherein said carbohydrate component comprises

(i) a rapidly absorbed fraction comprising glucose, one or more rapidly absorbed disaccharides containing a glucose unit, or a mixture thereof, wherein said fraction includes sucrose;
(ii) a moderately absorbed fraction comprising one or more moderately absorbed non-glucose monosaccharides, non-glucose-containing disaccharides, glucose-containing polysaccharides, or mixture thereof;
(iii) a slowly absorbed fraction comprising one or more slowly absorbed glucose-containing polysaccharides,; and

(d) fiber.

2. The composition of Claim 1 wherein the amount of protein component is 10 to 40% of total caloric value; the amount of fat component is 10 to 40% of total caloric value; and the amount of carbohydrate component is 5 to 85% of total caloric value.

3. The composition of Claim 1 wherein the amount of protein component is 15 to 30% of total calroic value; the amount of fat component is 15 to 35% of total caloric value; and the amount of carbohydrate component is 20 to 75% of total caloric value.

4. The composition of Claim 1 wherein the carbohydrate component comprises 1 to 95 wt % rapidly absorbed carbohydrate; 1 to 95 wt % moderately absorbed carbohydrate; and 1 to 95 wt % slowly absorbed carbohydrate.

5. The composition of Claim 1 wherein the carbohydrate component comprises 5 to 85 wt % rapidly absorbed carbohydrate; 5 to 85 wt % moderately absorbed carbohydrate; and 5 to 85 wt % slowly absorbed carbohydrate.

6. The composition of Claim 1 wherein the carbohydrate component comprises 20 to 75 wt % rapidly absorbed carbohydrate; 20 to 75 wt % moderately absorbed carbohydrate; and 20 to 75 wt % slowly absorbed carbohydrate.

7. The composition of Claim 1 wherein the rapidly absorbed carbohydrate is glucose, sucrose, maltose, or a mixture thereof; the moderately absorbed carbohydrate is fructose, mannose, maltodextrin, white flour, wheat flour or mixture thereof; and the slowly absorbed carbohydrate is raw corn starch, high amylose corn starch, a modified starch, or a mixture thereof.

8. The composition of Claim 1 wherein the rapidly absorbed carbohydrate is glucose, sucrose, or a mixture thereof; the moderately absorbed carbohydrate is fructose, mannose, maltodextrin, or mixture thereof; and the slowly absorbed carbohydrate is raw corn starch, high amylose corn starch, a modified starch, or a mixture thereof.

9. The composition of Claim 1 wherein the slowly absorbed carbohydrate is raw corn starch.

10. The composition of Claim 8 wherein the slowly absorbed carbohydrate is raw corn starch.

11. The composition of Claim 1 comprising 1 to 95 wt % fiber, based on total carbohydrate component.

12. The composition of Claim 1 comprising 5 to 85 wt % fiber, based on total carbohydrate component.

13. The composition of Claim 1 comprising 10 to 50 wt % fiber, based on total carbohydrate component.

14. use of:

(a) a protein component comprising 1 to 50 % of total caloric value;
(b) a fat component comprising 0 to 45% of total caloric value;
(c) a carbohydrate component comprising 1 to 90% of total caloric value wherein said carbohydrate component comprises

(i) a rapidly absorbed fraction comprising glucose, one or more rapidly absorbed disaccharides containing a

glucose unit, or a mixture thereof, wherein said fraction includes sucrose;
(ii) a moderately absorbed fraction comprising one or more moderately absorbed non-glucose monosaccharides; non-glucose-containing disaccharides,
glucose-containing polysaccharides, or mixture thereof;
(iii) a slowly absorbed fraction comprising one or more slowly absorbed glucose-containing polysaccharides,; and

(d) fiber.

in the manufacture of a nutritional composition for controlling blood glucose levels in a subject.

Patentansprüche

1. Nährmittel zur diätetischen Behandlung von Diabetes, umfassend

(a) einen Proteinbestandteil, der 1 bis 50 % des gesamten kalorischen Wertes ausmacht;
(b) einen Fettbestandteil, der 0 bis 45 % des gesamten kalorischen Wertes ausmacht;
(c) einen Kohlenhydratbestandteil der 1 bis 90 % des gesamten kalorischen Wertes ausmacht, wobei der Kohlenhydratbestandteil umfasst:

(i) eine schnell absorbierte Fraktion, die Glukose, wenigstens ein schnell absorbiertes Disaccharid mit einer Glukoseeinheit oder ein Gemisch davon umfasst, wobei die Fraktion Saccharose enthält;
(ii) eine mäßig schnell absorbierte Fraktion, die wenigstens ein mäßig schnell absorbiertes nicht-Glukose-Monosaccharid, nicht-Glukose-haltiges Disaccharid, Glukose-haltiges Polysaccharid oder ein Gemisch davon umfasst;
(iii) eine langsam absorbierte Fraktion, die wenigstens ein langsam absorbiertes Glukose-haltiges Polysaccharid umfasst; und

(d) Ballaststoff.

2. Mittel nach Anspruch 1, wobei die Menge des Proteinbestandteils 10 bis 40 % des gesamten kalorischen Wertes; die Menge des Fettbestandteils 10 bis 40 % des gesamten kalorischen Wertes; und die Menge des Kohlenhydratbestandteils 5 bis 85 % des gesamten kalorischen Wertes beträgt.

3. Mittel nach Anspruch 1, wobei die Menge des Proteinbestandteils 15 bis 30 % des gesamten kalorischen Wertes; die Menge des Fettbestandteils 15 bis 35 % des gesamten kalorischen Wertes; und die Menge des Kohlenhydratbestandteils 20 bis 75 % des gesamten kalorischen Wertes beträgt.

4. Mittel nach Anspruch 1, wobei der Kohlenhydratbestandteil 1 bis 95 Gew.% schnell absorbiertes Kohlenhydrat; 1 bis 95 Gew.% mäßig schnell absorbiertes Kohlenhydrat; und 1 bis 95 Gew.% langsam absorbiertes Kohlenhydrat umfasst.

5. Mittel nach Anspruch 1, wobei der Kohlenhydratbestandteil 5 bis 85 Gew.% schnell absorbiertes Kohlenhydrat; 5 bis 85 Gew.% mäßig schnell absorbiertes Kohlenhydrat; und 5 bis 85 Gew.% langsam absorbiertes Kohlenhydrat umfasst.

6. Mittel nach Anspruch 1, wobei der Kohlenhydratbestandteil 20 bis 75 Gew.% schnell absorbiertes Kohlenhydrat; 20 bis 75 Gew.% mäßig schnell absorbiertes Kohlenhydrat; und 20 bis 75 Gew.% langsam absorbiertes Kohlenhydrat umfasst.

7. Mittel nach Anspruch 1, wobei das schnell absorbierte Kohlenhydrat Glukose, Saccharose, Maltose oder ein Gemisch davon ist; das mäßig schnell absorbierte Kohlenhydrat Fructose, Mannose, Maltodextrin, Weißmehl, Weizenmehl oder ein Gemisch davon ist; und das langsam absorbierte Kohlenhydrat rohe Maisstärke, hochamylosehaltige Maisstärke, eine modifizierte Stärke oder ein Gemisch davon ist.

8. Mittel nach Anspruch 1, wobei das schnell absorbierte Kohlenhydrat Glukose, Saccharose oder ein Gemisch davon ist; das mäßig schnell absorbierte Kohlenhydrat Fructose, Mannose, Maltodextrin oder ein Gemisch davon ist;

und das langsam absorbierte Kohlenhydrat rohe Maisstärke hochamylosehaltige Maisstärke, eine modifizierte Stärke oder ein Gemisch davon ist.

9. Mittel nach Anspruch 1, wobei das langsam absorbierte Kohlenhydrat rohe Maisstärke ist.

10. Mittel nach Anspruch 8, wobei das langsam absorbierte Kohlenhydrat rohe Maisstärke ist.

11. Mittel nach Anspruch 1, umfassend 1 bis 95 Gew.% Ballaststoff, bezogen auf den gesamten Kohlenhydratbestandteil.

12. Mittel nach Anspruch 1, umfassend 1 bis 85 Gew.% Ballaststoff, bezogen auf den gesamten Kohlenhydratbestandteil.

13. Mittel nach Anspruch 1, umfassend 10 bis 50 Gew.% Ballaststoff, bezogen auf den gesamten Kohlenhydratbestandteil.

14. Verwendung eines

(a) Proteinbestandteils, der 1 bis 50 % des gesamten kalorischen Wertes ausmacht;
(b) Fettbestandteils, der 0 bis 45 % des gesamten kalorischen Wertes ausmacht;
(c) Kohlenhydratbestandteils, der 1 bis 90 % des gesamten kalorischen Wertes ausmacht, wobei der Kohlenhydrathestandteil umfasst:

(i) eine schnell absorbierte Fraktion, die Glukose, wenigstens ein rasch absorbiertes Disaccharid mit einer Glukoseeinheit oder ein Gemisch davon umfasst, wobei die Fraktion Saccharose enthält;
(ii) eine mäßig schnell absorbierte Fraktion, die wenigstens ein mäßig schnell absorbiertes nicht-Glukose-Monosaccharid; nicht-Glukose-haltiges Disaccharid; Glukose-haltiges Polysaccharid oder ein Gemisch davon umfasst;
(iii) eine langsam absorbierte Fraktion, die wenigstens ein langsam absorbiertes Glukose-halliges Polysaccharid umfasst; und

(d) Ballaststoffs,

zur Herstellung eines Nährmittels zur Kontrolle des Blutglukosespiegels bei einem Patienten.

Revendications

1. Composition nutritionnelle pour le traitement diététique du diabète comprenant:

(a) un composant protéique formant 1 à 50 % de la valeur calorique totale;
(b) un composant gras formant 0 à 45 % de la valeur calorique totale;
(c) un composant carbohydrate formant 1 à 90 % de la valeur calorique totale où ledit composant carbohydrate comprend

(i) une fraction rapidement absorbée comprenant du glucose, un ou plusieurs disaccharides rapidement absorbés contenant une unité de glucose, ou un mélange, où ladite fraction contient du saccharose;
(ii) une fraction modérément absorbée comprenant un ou plusieurs monosaccharides non glucose modérément absorbés des disaccharides ne contenant pas de glucose, des polysaccharides contenant du glucose ou des mélanges; et
(iii)une fraction lentement absorbée comprenant un ou plusieurs polysaccharides lentement absorbés contenant du glucose; et

(d) des fibres.

2. composition de la revendication 1 où la quantité du composant protéique est de 10 à 40% de la valeur calorique totale; la quantité du composant gras est de 10 à 40% de la valeur calorique totale; et la quantité du composant carbohydrate est de 5 à 85% de la valeur calorique totale.

3. Composition de la revendication 1 où la quantité du composant protéique est de 15 à 30% de la valeur calorique totale, la quantité du composant gras est de 15 à 35% de la valeur calorique totale et la quantité du composant carbohydrate est de 20 à 75% de valeur calorique totale.

4. Composition de la revendication 1 où le composant carbohydrate comprend 1 à 95% en poids du carbohydrate rapidement absorbé; 1 à 95% en poids du carbohydrate modérément absorbé; et 1 à 95% en poids du carbohydrate lentement absorbé.

5. Composition de la revendication 1 où le composant carbohydrate comprend 5 à 85% en poids du carbohydrate rapidement absorbé; 5 à 85% en poids du carbohydrate modérément absorbé et 5 à 85% en poids du carbohydrate lentement absorbé.

6. Composition de la revendication 1 où le composant carbohydrate comprend 20 à 75% en poids du carbohydrate rapidement absorbé; 20 à 75% en poids du carbohydrate modérément absorbé et 20 à 75% en poids du carbohydrate lentement absorbé.

7. Composition de la revendication 1 où le carbohydrate rapidement absorbé est glucose, saccharose, maltose, ou un mélange; le carbohydrate modérément absorbé est fructose, mannose, maltodextrine, farine blanche, farine de blé ou mélange; et le carbohydrate lentement absorbé et amidon de maïs brut, amidon de maïs à forte teneur en amylose, amidon modifié ou un mélange.

8. Composition de la revendication 1 où le carbohydrate rapidement absorbé est glucose, saccharose, ou un mélange; le carbohydrate modérément absorbé est fructose, mannose, maltodextrine, ou un mélange; et le carbohydrate lentement absorbé est amidon de maïs brut, amidon de maïs à forte teneur en amylose, amidon modifié ou un mélange, de la revendication 1 où le

9. Composition de la revendication 1 où le carbohydrate lentement absorbé est l'amidon de maïs brut.

10. Composition de la revendication 8 où le carbohydrate lentement absorbé est l'amidon de maïs brut.

11. Composition de la revendication 1 comprenant 1 à 95% en poids de fibres en se basant sur le composant carbohydrate total.

12. Composition de la revendication 1 comprenant 5 à 85% en poids de fibres en se basant sur le composant carbohydrate total.

13. Composition de la revendication 1 comprenant 10 à 50% en poids de fibres en se basant sur le composant carbohydrate total.

14. Utilisation de:

(a) un composant protéique formant 1 à 50 % de la valeur calorique totale;
(b) un composant gras formant 0 à 45 % de la valeur calorique totale;
(c) un composant carbohydrate formant 1 à 90 % de la valeur calorique totale où ledit composant carbohydrate comprend

(i) une fraction rapidement absorbée comprenant du glucose, un ou plusieurs disaccharides rapidement absorbés contenant une unité de glucose ou un mélange, où ladite fraction contient du saccharose;
(ii) une fraction modérément absorbée comprenant un ou plusieurs monosaccharides non glucose modérément absorbés, des disaccharides ne contenant pas de glucose, des polysaccharides contenant du glucose ou des mélanges; et
(iii)une fraction lentement absorbée comprenant un ou plusieurs polysaccharides lentement absorbés contenant du glucose; et

(d) des fibres,

dans la fabrication d'une composition nutritionnelle pour contrôler les niveaux de glucose dans le sang chez un sujet.